

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

[52 FR 30097, Aug. 12, 1987; 52 FR 49250, Dec. 30, 1987]

#### § 872.6100 Anesthetic warmer.

(a) *Identification.* An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 60 FR 38900, July 28, 1995]

#### § 872.6140 Articulation paper.

(a) *Identification.* Articulation paper is a device composed of paper coated with an ink dye intended to be placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994]

#### § 872.6200 Base plate shellac.

(a) *Identification.* Base plate shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989]

#### § 872.6250 Dental chair and accessories.

(a) *Identification.* A dental chair and accessories is a device, usually AC-powered, in which a patient sits. The device is intended to properly position a patient to perform dental procedures. A dental operative unit may be attached.

(b) *Classification.* Class I. The dental chair without the operative unit device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994]

#### § 872.6290 Prophylaxis cup.

(a) *Identification.* A prophylaxis cup is a device made of rubber intended to be held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989]

#### § 872.6300 Rubber dam and accessories.

(a) *Identification.* A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting the tooth through the hole in the center. The device includes the rubber dam, rubber dam